

LABEL, IN PART: (Bottle) "Foille Emulsion A Protective Dressing. Analgesic-Antiseptic. Ingredients: Benzocaine, Carbolic Acid (Less than 2 Percent), Calcium Oleate, Calcium and Potassium Iodides, Oxyquinoline Base, Calcium Thiosulfate and sulphur in a Vegetable Oil Base * * * Directions: Apply liberally to gauze compress or directly to wound area."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form as are necessary for the protection of users. The article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply liberally to gauze compress or directly to wound area" and (brochure entitled "Burns") "Dressing saturated with Foille Emulsion should be applied directly to the wound and the dressing kept moist with Foille. * * * In some cases, * * * it may be appropriate to continue with the original dressings for a longer period of time by frequently saturating them with Foille in order to keep the area moist, soft, and pliable. Such treatment may be continued either with or without changing the dressings until healing is complete or until conditions are satisfactory for grafting. * * * Foille Emulsion is applied directly to the injured areas either by pouring, spreading with a camel's-hair brush or spraying with a special atomizer. Under open, cradle treatment method, Foille Emulsion is reapplied at regular intervals, either with saturated compresses or direct without benefit of dressings as indicated above."

DISPOSITION: April 28, 1949. Default decree of condemnation and destruction.

2712. Misbranding of Foille Emulsion. U. S. v. 9 Bottles, etc. (F. D. C. No. 26953. Sample Nos. 53430-K, 53431-K.)

LABEL FILED: March 24, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about January 17, February 22, and March 14, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 9 16-ounce bottles, 15 4-ounce bottles, 279 1½-ounce bottles, 2 1-gallon bottles, and 6 1-quart bottles of *Foille Emulsion* at Birmingham, Ala., together with 2 brochures entitled "Burns" which were delivered by a representative of the shipper.

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NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply

liberally to gauze compress or directly to wound area" and (brochure entitled "Burns") "Dressing saturated with Foille Emulsion should be applied directly to the wound and the dressing kept moist with Foille. * * * In some cases, * * * it may be appropriate to continue with the original dressings for a longer period of time by frequently saturating them with Foille in order to keep the area moist, soft and pliable. Such treatment may be continued either with or without changing the dressings until healing is complete or until conditions are satisfactory for grafting. * * * Foille Emulsion is applied directly to the injured areas either by pouring, spreading with a camel's-hair brush or spraying with a special atomizer. Under open, cradle treatment method, Foille Emulsion is reapplied at regular intervals, either with saturated compresses or direct without benefit of dressings as indicated above."

DISPOSITION: April 25, 1949. Default decree of condemnation and destruction.

2713. Misbranding of syrup urethane. U. S. v. 9 Bottles * * *. (F. D. C. No. 26649. Sample No. 9128-K.)

LIBEL FILED: March 15, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 5, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 9 16-ounce bottles of *syrup urethane* at Hackensack, N. J.

LABEL, IN PART: "Syrup Urethane—M. R. T. * * * Each teaspoonful (5-cc) contains urethane 4 Grs. in a flavored syrup base."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling, namely, "1 teaspoonful every 3 or 4 hours," since the administration every 3 or 4 hours of 1 teaspoonful of the article containing the stated amount of urethane is capable of causing leucopenia.

Violation of Section 505, the article was a drug which should not have been introduced into interstate commerce, since it was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: April 25, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2714. Misbranding of yeast capsules. U. S. v. 129 Boxes * * *. (F. D. C. No. 26618. Sample No. 27878-K.)

LIBEL FILED: February 24, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 30, 1948, from Detroit, Mich.

PRODUCT: 129 boxes each containing 50 *yeast capsules* at St. Louis, Mo. The product was offered orally by its distributor, Albert Christy, during the course of lectures delivered by him at St. Louis on January 11, 1949, for constipation and to introduce flora into the intestines, to remove pin worms and hook worms

*See also Nos. 2711, 2712.